Avantect | PANCREATIC CANCER TEST

CLIA LAB ID: 05D2249973

1. PATIENT INFORMATION

Patient Name_____

Date of Birth_____ MRN/Other Patient ID_____ Sex at Birth_____

2. ORDERING PROVIDER

Name_____

Institution/Account Name_____

3. SPECIMEN INFORMATION

Collection Date_____

Specimen Received Date_____

Specimen ID_____

Specimen Type_____

Report Date_____

RESULTS

DETECTED

An ABNORMAL Epigenomic Signal was DETECTED.

- This signal in circulating cell free DNA has been associated with the presence of malignancy in the pancreas.
- It could also represent other abnormal conditions of the pancreas including Intraductal Papillary Mucinous Neoplasm (IPMN) and pancreatitis. There is a small possibility it could represent the detection of a malignancy outside the pancreas.
- Consultation with a physician or licensed genetic professional is recommended.
- Additional clinical and radiologic evaluation is required to establish a diagnosis.

ABOUT THE TEST

- The test is intended to evaluate the presence or absence of a signal in circulating cell-free DNA (cfDNA) associated with *pancreatic cancer* by assessing epigenomic and genomic signals derived by next generation sequencing (NGS) of 5-hydroxymethylation (5hmC) enriched cfDNA and total cfDNA[2].
- Based on a case-control validation study of pancreatic cancer (n=102) and non-cancer subjects (n=2048), the sensitivity for detection of pancreatic cancer for this test is 66.7% (95% CI: 56.6% - 75.7%) and the specificity of this test is 96.9% (95% CI: 96.0% - 97.6%). Further test performance information is available upon request.
- In **newly diagnosed** (within 36 months) **patients with type 2 diabetes** over the age of 50 years, the risk of pancreatic cancer is up to **eight-fold** greater compared to the general population[3]. Nearly 25% of all new diagnoses of pancreatic cancer in the United States are identified in newly diagnosed type 2 diabetes patients[1].

LIMITATIONS AND REGULATORY

Not all patients with pancreatic cancer will be classified as "signal detected," and some patients without pancreatic cancer will have a "signal detected" result. The Avantect Pancreatic Cancer Test is intended for clinical use and should not be regarded as investigational or for research. The test has been developed, and the performance characteristics determined, by the ClearNote Health Clinical Laboratory, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. The Avantect Pancreatic Cancer Test has not been cleared or approved by the U.S. Food and Drug Administration.

References: **1.**Chari ST, Leibson CL, Rabe KG, et al. Probability of pancreatic cancer following diabetes: a population-based study. Gastroenterology 2005;129:504–511. **2.**Guler GD, Ning Y, Ku CJ, Phillips T, McCarthy E, Ellison CK et al. Detection of early-stage pancreatic cancer using 5-hydroxymethylcytosine signature in circulating cell free DNA. *Nat Commun.* 2020 Oct 19;11(1):5270. doi: 10.1038/s41467-020-18965-w. PMID: 33077732; PMCID: PMC7572413. **3.**Huxley R, Ansary-Moghaddam A, Berrington De-González A, et al. Type-II diabetes and pancreatic cancer: a meta-analysis of 36 studies. Br J Cancer 2005;92:2076–2083.

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